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WRIST IMPLANT APPARATUS AND METHOD

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Description

WRIST IMPLANT APPARATUS AND METHOD

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Related Applications

This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/411,824, filed September 18, 2002; the disclosure of which is incorporated herein by reference in its entirety.

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Technical Field

The present subject matter relates to prosthetic implants and more particularly to wrist implant apparatuses and methods utilizing a wrist implant with a geometry that closely matches that of the natural wrist, which minimizes bone resection, and which can be installed in a manner to minimize future implant failure.

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Background Art

The replacement of degenerated natural joints with man-made prosthetic replacements is well known, including the replacement of the wrist joint. Prior to 20 the introduction of prosthetic joint replacement, patients with wrist diseases such

as radio-carpal arthritis were often treated with a fusion procedure. Fusion typically involved an implantable joint replacement that prevented articulation of the wrist. Fusion however, proved to be less than satisfactory since it left the patient with no movement in the wrist.

5 Existing prosthetic wrist implants have a number of drawbacks. Because of the size needed to achieve the necessary strength, wrist implants have typically required excessive amounts of bone to be resected. For example, in these implants relatively large and lengthy implant stems were inserted into the radius and carpal bones. This significantly weakened the bones making them more
10 susceptible to post-operative fracture. Furthermore, once fracture occurs, because of the significant loss of bone due to resection, there may not be enough bone left to permit a satisfactory fusion procedure. This may leave a patient without any avenue of treatment, not even fusion.

Another drawback with prior prosthetic wrist implants is that they do not
15 provide the patient with acceptable functionality. Part of the problem is that these implants have not adequately matched the geometry of the natural wrist. As a result, flexion and extension of the hand return to a natural position, and range of motion have all been less than optimum, and the patient is left with less functionality of the implanted wrists than with a natural wrist.

20 Another difficulty with prior wrist implants involves the means of attaching the implant to the radius and carpal bones. If the attachment is not secure enough, or the implant itself is not strong enough, the stability of the attachment

may not be adequate under normal use of the wrist. Because of this, larger implants and implant stems have been used to attach the implant components into the bone. However, as discussed above, this results in more resection and weakening of the bone. As a result of the above issues, existing prosthetic wrist

5 implants have not always achieved adequate levels of patient satisfaction and have sometimes resulted in unacceptable complication rates.

Another problem with wrist implant procedures is the unavailability of special instruments for performing the implant operations. Tools currently available make excavation of a hole, which is cut into the bone to position the

10 implant, difficult and imprecise. As a result, malrotation of the tool can occur which results in misalignment of the implant. Further, specialty guides are unavailable to assist in alignment of a cutting blade during resection of the bone into which the implant is to be fitted. The absence of a guide during the actual resection requires the surgeon performing the resection to "eyeball" the area to be resected. This

15 may result in excess bone material being removed during the resection.

A final problem with prior art wrist implants is the manner in which the implant is pieced together and functions, and the potential to limit the life of the implant due to particle contamination. U.S. Patent Nos. 5,702,470 and 6,059,832 each describe a prosthetic wrist implant comprising a prosthetic wrist implant

20 disposed between a patient's radius and carpal complex bones. The implant includes a radial implant component, a carpal bone implant component, and an articulating bearing member that is fastened to the carpal bone implant and

slidingly engages the radial implant. While these prior art devices may work for their intended purposes, two primary areas could be improved. First, the articulating bearing member of these prior art patents is designed to connect laterally (sideways from the dorsal plane) onto the carpal bone implant component

5 through the use of slots on the bearing member that connect with tabs on the carpal implant. This joining action requires the surgeon to use a large, cumbersome tool to grasp both the bearing member and the carpal implant and slide them together laterally for a tight fit. Second, once the bearing member and carpal implant are joined, the metal surface of the carpal implant is exposed

10 underneath the bearing member. At extreme flexions of the wrist, the metal radial implant can rub against the metal exposed portion of the carpal implant, causing the shedding of metallic particulate matter. This metal particulate matter can contaminate surrounding tissue and lead to cell degeneration and death. Once surrounding tissue is damaged, the implant is loosened and eventually this

15 loosening can lead to implant failure.

Thus, it would be desirable to provide improved prosthetic wrist implants, and methods that overcome some or all of the above-discussed problems. In particular it would be desirable to provide wrist implants with a geometry which matches that of a natural wrist and which affords the patient a natural range of

20 motion, natural flexion and natural extension of the hand. Furthermore, it would be desirable to provide prosthetic wrist implants that are small enough to minimize the bone resection required. It further would be desirable to provide wrist implants that

function in a manner so as to minimize effort required to join functioning components of the implants and to also minimize the chances of metal-on-metal contact of implant components and subsequent implant failure. It would also be desirable to provide an improved methods for attaching prosthetic wrist implants

5 which provide a stable and strong attachment to the bone without requiring excessive loss of bone through resection or drilling.

Summary

The prosthetic wrist implants and methods disclosed herein combine a

10 number of positive design features to provide optimal range of motion with acceptable flexion and extension of the hand. This is accomplished by incorporating an implant with a unique geometry matching that of the natural wrist.

For example, an inclined articular surface of a radial component of the implant mimics the articular surface of a radius. In addition, a carpal component and

15 bearing component of the wrist implant are designed to linearly engage with the use of simple tools so that the bearing component completely covers certain exposed portions of the carpal component, eliminating metal-on-metal contact between the radial component and the carpal component and minimizing future implant failure. The wrist implant empowers the surgeon the option to select the

20 best method of implant fixation for the patient by utilizing either bone cement for cement fixation or implant interference fit for press-fit fixation. The carpal plate is primarily secured to the carpus bones by way of screws with the addition of either

bone cement of press-fit fixation methods. The radial implant is secured to the distal radius bone by either bone cement or press-fit fixation methods. This, coupled with a range of implant sizes, from extra-small to large, allows the surgeon to determine and select the optimal fit with minimal bone resection. These aspects

5 result in a stronger attachment as well as stronger bone structure post-operatively.

In accordance with one embodiment of the presently disclosed subject matter, a prosthetic wrist implant comprises a radial component including a base member having an upper bearing surface and a lower surface having an elongated radial stem for fixation to a radius bone. The elongated radial stem can be in an

10 off-center position in relation to the centerline of the lower surface. The wrist implant also includes a carpal component including a substantially planar base member having an upper surface having an elongated carpal post member for fixation to one or more carpal bones and a lower surface with at least one socket protrusion extending therefrom. Additionally, the wrist implant includes an

15 articulating bearing component for placement between the radial and carpal components, the bearing component having an upper surface defining at least one socket recess and a lower bearing surface for cooperative engagement with the upper bearing surface of the radial component. In the preferred embodiment, the socket protrusion of the carpal component is adapted to linearly engage the socket

20 recess of the bearing component to desirably limit rotational and translational movement of the carpal component relative to the bearing component.

A method for implanting a prosthetic wrist implant in a wrist area is also provided comprising surgically opening a patient's wrist area and exposing a radius bone and carpal bone complex bones, resectioning the radius bone, broaching the radius bone, selecting a radial component and positioning the

5 selected radial component within the radius bone broach and adjacent to the radius bone so that the lower surface of the radial component abuts the resected radius bone. The method also includes resectioning the carpal bone complex, selecting a carpal component and positioning the selected carpal component adjacent to the carpal bone complex so that the upper surface of the carpal

10 component abuts the resected carpal bone complex. Once the radial and carpal components have been secured to the radius bone and carpal bone, respectively, the method includes selecting an articulating bearing component and linearly engaging the bearing component with the carpal component to desirably limit rotational and translational movement of the carpal component relative to the

15 bearing component. Finally, the wrist area can then be surgically closed.

Accordingly, it is an object to provide improved prosthetic wrist implants and methods designed to minimize effort required to join functioning components and to also minimize wear and dislocation on implant components that can result in implant failure.

20 An object having been stated hereinabove, and which is addressed in whole or in part by the present subject matter, other objects will become evident as the

description proceeds when taken in connection with the accompanying drawings as best described hereinbelow.

Brief Description of the Drawings

- 5 Figure 1 is a drawing of the bones of the left hand dorsal surface;
Figures 2A – 2G are side elevation, front elevation, and perspective views of the components of an embodiment of the wrist implant apparatus;
Figures 3A – 3G are various views of the radial implant component of the wrist implant apparatus;
- 10 Figures 4A – 4F are various views of the carpal implant component of the wrist implant apparatus;
Figures 5A – 5E are various views of the articulating bearing component of the wrist implant apparatus;
- 15 Figures 6A and 6B are a plan view and side elevation view of tools used for preparation of the radius in accordance with a method of the present disclosure;
Figure 7A and 7B are perspective views of broaching tools used for preparation of the radius in accordance with a method of the present disclosure;
- 20 Figures 8A and 8B are perspective views of tools used for insertion and extraction of a trial radial implant component in accordance with a method of the present disclosure;
Figures 9A – 9D are perspective views of tools used for preparation of the carpus in accordance with a method of the present disclosure;

Figures 10A – 10D are perspective views of tools used for insertion of a carpal implant component in accordance with the method of the present disclosure;

Figures 11A – 11H show x-ray templates used for four sizes of the wrist
5 implants;

Figure 12 is a phantom view of the left hand showing a surgical incision utilized in accordance with a method of the present disclosure;

Figure 13 is a phantom view of radius and ulnar bones showing ulnar resection;

10 Figures 14A – 14C are perspective views showing radius preparation;

Figures 15A and 15B are perspective views showing radius broaching;

Figures 16A and 16B are perspective views showing initial carpus preparation;

Figures 17A and 17B are perspective views showing carpus resecting;

15 Figures 18A and 18B are perspective views showing trial carpal implant component installation;

Figure 19 is a perspective view of the bones of the left hand with a trial wrist implant in place showing range of motion of the wrist;

Figure 20 is a perspective view of bones of the left hand illustrating fixation
20 of the carpal component;

Figures 21A – 21B are perspective views of the radius and ulnar bones illustrating a method of fixation of the radial component;

Figure 22 is a pre-operative x-ray of a patient suffering from radio-carpal arthritis;

Figure 23 is an x-ray of the patient's wrist shown in Figure 22 at 32 months post-operative; and

5 Figures 24 – 30 are various views of a wrist implant apparatus in accordance with an alternative embodiment of the present disclosure.

Detailed Description

The present subject matter discloses prosthetic wrist implants and methods.

10 The prosthetic wrist implants and methods disclosed herein minimize bone resection and allow natural articulation of the hand. An implant is utilized with a geometry that matches that of a natural wrist to afford a normal range of motion to the patient and also is designed to linearly engage and minimize future implant failure. An inclined articular surface of the radial component of each implant
15 mimics the articulate surface of the distal radius bone. The small size and method of attachment of the implants minimize bone resection. The carpal component and bearing component are designed to linearly engage with the use of simple tools so that the bearing component can completely cover certain exposed portions of the carpal component, eliminating metal-on-metal contact between the
20 radial component and the carpal component and minimizing future implant failure.
The wrist implant may utilize screws, bone glue, or press-fit properties for

attachment of the carpal component, the radial component, or both, and provides a stable and strong attachment with minimal bone removal.

Referring now to Figure 1, the bones of the left hand are shown viewing the dorsal surface and including portions of the radius and ulna. In particular, Figure 1

5 shows the bones of the wrist **10** including the radius **12**, the ulna **14**, the scaphoid **16**, the lunate **18**, the triquetrum **20**, the hamate **22**, the capitate **24**, the trapezoid **26** and the trapezium **28** bones. Pisiform bone **30** is also shown. These eight bones **16-30** make up the carpus bone complex **32** of the hand. Additional bones that will not be discussed in detail include the metacarpal bones **34** and the

10 phalanges bones **36**.

It will be appreciated that scaphoid **16** and lunate **18** bones articulate with radius **12** to provide motion of the wrists. In a variety of wrists disorders, such as radio-carpal arthritis, patients may experience discomfort, pain and difficulty in moving the wrist. Prior surgical treatment of this condition involves fusion, which,

15 as discussed previously, will prevent articulation of scaphoid **16** and lunate **18** bones with radius **12**. In this procedure, a patient may have pain alleviated, but is left without motion of the wrists.

Subsequently, prosthetic wrist implants have been developed to provide an artificial articulating surface for the wrists. However, previous implants have

20 suffered from a number of drawbacks such as those discussed above, including limited range of motion and excessive bone resection which significantly weakens

the bones in question and subjects them to a greater likelihood of fracture. Additionally, prior art prosthetic wrist implants have had cumbersome methods of apparatus assembly and have experienced dissimilar metal-on-metal contact between apparatus pieces, resulting in generation of metal particulate debris and

5 implant failure.

Referring now to Figures 2A and 2B one embodiment of the wrist implant apparatus of the present invention, generally designated **WI**, is shown. In Figure 2A, a side view of wrist implant **WI** shows three components including: a radial implant component, shown generally as **40**, that can be inserted into the distal 10 radius bone **12** after bone osteotomy; a carpal implant component, shown generally as **44**, that can be inserted into the proximal carpus bone complex **32** after bone osteotomy; and an articulating bearing component, shown generally as **42**, that can connect rigidly to carpal component **44** and articulate unconstrained with radial component **40**. Similarly, Figure 2B shows these three components in a 15 front view. It is notable that, as best as seen in the side view, radial implant component **40** of prosthetic wrist implant **WI** incorporates a bearing guide base member **46** which is tilted with respect to the axis of radius bone **12** into which a radial stem **48** is inserted. Carpal implant component **44** includes a planar base member **49** and a post member **50** that is inserted into the capitate **24** of carpus 20 bone complex **32**. As shown in Figures 2C – 2E, bearing component **42** is mounted ridgedly to planar carpal base member **49** and provides a low friction

surface that is articulated against bearing guide base member **46**. As shown in Figures 2F and 2G, wrist implant **WI** may further include bone screws **132** for fixation of carpal implant component **49**, primarily to hamate **22**, and trapezoid **26** of carpus bone complex **32**.

- 5 Referring now to Figures 3A – 3E, one embodiment of radial implant component **40** is shown in more detail. Figures 3A – 3D show bearing guide base member **46** that includes an upper bearing surface **52** and a lower surface **54**. Upper bearing surface **52** is substantially concave or curved in a preferred embodiment. As shown in Figure 3D, this curved surface **52**, in the preferred embodiment, can have a major radius preferably ranging from about 26.0 to about 10 35.3 mm and is highly polished to allow direct contact with carpal bearing component **42** as will be described in more detail below. Lower surface **54** can include a first flat portion **55** and a second flat portion **56** tilted at an angle with respect to first flat portion **55**. First flat portion **55** of bearing guide base member 15 **46** is preferably disposed at about a 15 degree angle to a plane perpendicular with respect to the axis of the radius **60** wherein first flat portion **55** abuts against the surface of radius bone **12** as described in more detailed below. Second flat portion **56** of bearing guide base member **46** is preferably disposed at about a 25 degree angle to a plane perpendicular with respect to the axis of the radius **60**. 20 The angling of first flat portion **55** and second flat portion **56** allows radial

component **40** to be placed in the patient's wrist without resecting or cutting ulna bone **14**.

As shown in Figures 3B and 3C, an elongated radial stem or post **48** is attached to and extends from lower surface **54**. Radial stem **48** further includes a

5 lower stem section **68** and an upper stem section **69**. Stem **48** also is preferably generally tapered from lower surface **54** at surfaces **58, 62, 64**, and **66** as shown in Figure 3B. As shown in Figure 3C, radial stem **48** preferably tapers down from its attachment from the shape shown at upper stem section **69**, where it is attached to lower surface **54**, down to a rounded end portion **67**. Additionally, radial stem **48** is

10 axis-symmetrical and is preferably dorsal off-center from radial centerline **71** preferably in the amount ranging from about 3.35 to about 4.60 mm as needed for either a right or left radial bone. This offset axis-symmetrical radial stem **48** improves alignment for right or left wrist placement in order to improve radial component **40** stability in the intramedullary canal of radius bone **12** and to

15 improve surgical technique.

Figure 3E is a side sectional view of the radial implant component **40** showing that upper bearing surface **52** along the side axis has a minor radius preferably ranging from about 7.10 to about 9.75mm. In the preferred embodiment, radial implant component **40** is made of cast material such as

20 CoCrMo as per specification ASTM F75. However, it will be appreciated by those

skilled in the art that other materials having sufficient strength and biocompatibility may also be employed.

Referring to Figures 3F and 3G, as can be appreciated by those of skill in the art, portions of radial component **40** may further preferably contain a porous 5 coating of CoCrMo alloy spherical powder as per ASTM F75 and F1377 requirements for the aid in osteointegration of the implant and to aid in allowing radial component **40** to be in a press-fit relationship with radial bone **12**. The porous coating can comprise metal beads defined by sieve size –50+75 consisting of two layers with a coating thickness (average) of 0.4276 mm (0.0168 in) wherein 10 the porous coating is bonded to the substrate of radial component **40** by a sintering process. Typically, the beaded porous coating will cover upper stem section **69** of radial stem **48** and will also cover first flat portion **55** of lower surface **54**, as these portions of radial component **40** are in contact with cancellous bone within radial bone **12**. In order to accommodate the different wrist sizes found in a 15 variety of patients, radial component **40** can be made in four sizes ranging from extra-small to large.

Referring now to Figures 4A – 4F, an embodiment of carpal implant component **44** is shown. As shown in Figures 4A – 4C, carpal component **44** includes a planar base member **49** including a lower surface **70**, and upper surface 20 **90**, and outer edge **91**. While lower surface **70** has at least one, preferably cylindrical, locking socket post or protrusion **72** attached to and extending

therefrom, lower surface 70 is shown in an advantages embodiment having two locking socket protrusions 72. Locking socket protrusions 72 also preferably have tapered holes 76, with spherical radii at the base of the hole, through which attachment screws 132 (described below) can be inserted into carpal bone

5 complex 32. As shown in more detail in Figure 4B, locking socket protrusions 72 preferably each include a raised socket ring or external lip 80 which surrounds the circumferences of socket protrusions 72. In the preferred embodiment, each socket ring 80 is configured to engage with a groove in a socket recess in carpal bearing component 42 as described in more detail below.

10 Elongated carpal post member 50 protrudes preferably perpendicularly from upper surface 90 of carpal implant component 44. Figure 4C shows the location of tapered holes 76 and post 50 of a preferred embodiment when viewed from upper

surface 90 of carpal implant component 44. Referring now to Figure 4D, carpal post 50 is shown including a porous beaded coating of Commercially Pure (C.P.)

15 Grade 2 Titanium spherical powder as per ASTM F67 and F1580 requirements, which serves to secure post 50 into carpal bone complex 32 once it is implanted by enhancing the press-fit relationship between post 50 and carpal bone complex 32 and by aiding in osteointegration of the implant. The porous coating can be metal beads defined by sieve size -50+70 and be applied in two layers with a coating

20 thickness (average) of about 0.386 mm (0.0152 in), covering the entire carpal post 50 and may additionally cover the entire surface of upper surface 90 (Figure 4C).

The porous coating is bonded to the substrate of carpal post **50** by a sintering process.

As described in more detail below, post **50** is preferably inserted into capitate bone **24** and may include bone screws **132** (Figures 4E and 4F) that are 5 inserted into holes **76** are screwed into hamate **22** and trapezoid bones **26**. Carpal implant component **44** is preferably made of titanium such as Ti-6Al-4V ELI as per specification ASTM 136, although it will be appreciated by those skilled in the art that other materials having sufficient strength and biocompatibility may also be employed. In order to accommodate the different wrist sizes found in a variety of 10 patients, carpal component **44** can be made in multiple, such as four, sizes ranging from extra-small to large.

Referring now to Figures 5A – 5E, a preferred embodiment of articulating bearing component **42** is shown. Bearing component **42** imitates the articulation of lunate **18** and scaphoid **16** bones and is adapted for placement between radial 15 component **40** and carpal implant component **44**. Bearing component **42** as seen in Figure 5A in side end view includes an at least substantially planar upper surface **102** and preferably has a convex articulating lower bearing surface **96** which, in a preferred embodiment, can have a minor radius ranging from about 7.10 to about 9.75 mm. The convex radii of lower bearing surface **96** is designed 20 to match the corresponding concave radii of upper bearing surface **52** of radial component **40**. These matching radii allow a total line (surface to surface) contact

between bearing component **42** and radial component **40** during all implant rotations (radial – ulnar and flexion – extension) and torsional rotation. This constant surface-to-surface contact between bearing component **42** and radial component **40** results in superior stability of the apparatus and decreased material

5 wear.

As shown in Figures 5A – 5E, carpal bearing upper surface **102** includes an extended skirt **107** around the perimeter of and extending from upper surface **102**. Skirt **107** may be constructed continuously around the perimeter of upper surface **102** or may be constructed intermittently with gaps around the perimeter of upper 10 surface **102**. Additionally, skirt **107** comprises a skirt upper edge **105** defined as the edge of the skirt extended furthest away from upper surface **102**. As will be described in more detail hereinbelow, when bearing component **42** is fully engaged with carpal component **44**, skirt **107** at least substantially surrounds carpal component outer edge **91** and skirt upper edge **105** is disposed upon a 15 plane that is at least substantially coplanar with upper surface **91** of planer base member **49** of carpal component **44**.

While upper surface **102** also preferably includes at least one socket recess **104**, two socket recesses **104** are shown in Figures 5C and 5D, with end socket recess **104** having an internal socket groove portion **106**. When installing or fitting 20 bearing component **42** onto carpal implant component **44**, each socket recess **104** engages with a locking socket protrusion **72** as bearing component **42** is

compressed onto lower surface **70** of carpal implant component **44** through a linear compressive impaction load directed on carpal bearing component **42** towards carpal implant component **44**. When fully engaged across lower surface **70**, socket external lip or ring **80** of carpal locking socket protrusions **72** will fully 5 engage with socket groove portion **106** of socket recesses **104** thereby preventing bearing component **42** from separating from lower surface **70** of carpal implant component **44** once installed.

Extended skirt **107** extending from upper surface **102** extends around carpal component planar base member **49**, when fully fitted together, such that skirt **107** 10 at least substantially surrounds carpal component outer edge **91**. When bearing component **42** and carpal component **44** are fully engaged, skirt upper edge **105** is disposed upon a plane that is substantially coplanar with the upper surface **90** of base member **49** of carpal component **44**. This fitting of skirt **107** around carpal component base member **49** can prevent any metal-on-metal contact between 15 radial component **40** and carpal component **44**. A problem encountered by prior art wrist implants, metal-on-metal contact between radial component **40** and carpal component **44** can lead to generation of metal particulate which can lead to contamination of tissue, degenerating the life of the tissue and leading to cell death. This degenerating effect can lead to implant loosening and failure. 20 Therefore, the use of a linear attachment mechanism for attaching carpal

component **44** and bearing component **42**, along with protective skirt **107** leads to a longer lasting implant with lower risk of implant failure.

Articulating bearing component **42** in the preferred embodiment is made from ultra high molecular weight polyethylene (UHMWPe). However, it will be
5 appreciated that other low friction polymeric materials may also be employed. In addition, other materials may also be used in some situations. In order to accommodate the different wrist sizes found in a variety of patients, bearing component **42** can be made in four sizes ranging from extra-small to large. Additionally, in order to accommodate the extent of radius bone **12** resection,
10 bearing component **42** preferably has three variations of height: standard, +1 (2.5 mm taller), and +2 (5 mm taller).

Referring now to Figures 6A and 6B, tools used to determine the correct angle and complete resection of the radial bone are shown. Radial alignment guide rod **108** is for insertion into the medullary canal of radius bone **12**. Radial guide bar **110** is slid over radial alignment guide rod **108** and is used for placement
15 of radial cutting block **112** over the distal end of radius bone **12**. Once radial cutting block **112** is in the proper placement for resecting, K-wires **114** can be inserted through a series of 4 columns of holes in radial cutting block **112** to hold it in place. Each row of holes can have three holes to allow proximal relocation of
20 the cutting guide. This is to permit additional parallel bone cuts at a distance of about 2.5 mm between each row of holes.

Referring now to Figures 7A and 7B, tools used to broach the radial bone for insertion of radial implant component **40** are shown. A proper size broach head **116** is selected depending on the size hole needed for insertion of the proper size radial implant component **40** (extra-small, small, medium, large). Broach head **116**

- 5 is inserted into broach handle **118** and the resulting combination is slid over radial alignment guide rod **108** and abutted against the resected head of radius bone **12**. A mallet (not shown) is used to drive broach head **116** into radius bone **12** to create the broach.

As described hereinabove, radial alignment guide rod **108** is entered into

- 10 the distal radius and travels down the medullary canal of radius bone **12**. This concentric alignment of guide rod with the intramedullary canal directs the optimal placement of radial broach head **116**. Prior art prosthetic wrist implant methods included the placement of a radial component center stem in the center of the distal radius with no guide rod, which was preceded with the reaming of an
- 15 unguided center broach hole that would sometimes impact the volar cortex wall and create cortex fracture. The anatomy of the distal radius is that the dorsal side remains uniform in thickness to the intramedullary canal while the volar cortex flairs out similar to a funnel to the volar surface with a thin bone cortex. Therefore, the novel combination of the use of a radial alignment guide rod **108** that guides
- 20 broach head **116** with the axis-symmetrical and dorsal off-center radial stem **48**

creates a radial implant component **40** that is directed for proper axial alignment and prohibited from possible volar cortex fracture.

Referring now to Figures 8A and 8B, tools used to insert and extract trial versions of radial implant component **40** and insert the permanent radial implant 5 component **40** into radius bone **12**, are shown. Radial impactor **120** is designed to engage upper bearing surface **52** of radial implant component **40** as shown and drive radial component **40** into radius bone **12**. If radial component **40** is to be removed, such as during trial runs prior to implantation of the permanent implant, radial T-handle extractor **122** can be used to matingly engage radial component **40** 10 and extract the same out of radius bone **12**. This mating engagement between radial T-handle extractor **122** and radial component **40** can be through threaded male and female portions or any other mating system known to those of skill in the art.

Referring now to Figures 9A – 9D, tools used to determine the correct angle 15 and complete resection of carpus bone complex **32**, are shown. Carpal modular drill guide **123** and carpal modular drill guide plate **124** are used for positioning carpal drill bit **125** for production of a guide bar hole in the carpal capitate head. The yoke feature at the end of carpal modular drill guide **123** directs an axial alignment of carpal drill bit **125** to the opposite end of the drill bit guide hole. The 20 Carpal modular drill guide **123** centers the axial alignment of the drill bit to drill to the center of metacarpal bones **34**. Upon insertion of the guide hole, carpal guide

bar **127** is inserted into the hole and carpal cutting guide block **126** is mounted onto carpal guide bar **127** and slid into proper position for resecting. Once carpal cutting guide block **126** is in the proper position for resecting, K-wires **114** can be inserted through holes in carpal cutting block **126** to hold it in place. Carpal cutting
5 guide bar **127** can have a series of 4 columns of holes, two in each column, for relocation of the carpal cutting guide bar. This is to permit additional parallel bone cuts at a distance of about 2.5 mm between each row of holes.

Referring now to Figures 10A – 10D, tools used to insert carpal implant component **44** into carpal bone complex **32**, are shown. Carpal impactor **120** is
10 designed to engage lower surface **70** of carpal implant component **44** as shown and drive carpal component **44** into carpal bone complex **32** for permanent fixation. Screwdriver **129** is used to insert bone screws **132** for complete fixation.

A surgical technique of implanting the prosthetic wrist implant **WI** will now be described in connection with Figures 11A - 23.

15 Figures 11A – 11H illustrate x-ray templets used in conjunction with prosthetic wrist implant **WI** to ensure proper sizing (for example extra-small, small, medium and large) of the implant prior to the surgical operation as discussed in more detail below. Extra-small, small, medium and large sizes of the implants are shown in two views in the x-ray template. Upon x-ray viewing, radial component
20 **40** should not extend more than 2 mm over the margins of the carpus at the level

of the osteotomy. In general, the surgeon should select the smaller implant size when deciding between two sizes.

Prior to performing the prosthetic wrist implant surgical procedure, the patient is placed under general or regional anesthesia. Alternatively auxiliary block 5 anesthesia may be used. A non-sterile tourniquet is used to obtain a bloodless field. A strip of transparent adhesive film is applied to the dorsum of the hand and wrist to protect the skin from damage during instrumentation. Fluoroscopy is a helpful adjunct to confirm positions of the guides and implants. Save all resected bone during the procedure for use in bone grafting the carpus to achieve an 10 intercarpal arthrodesis.

Referring now to Figure 12 a longitudinal dorsal incision **128** is made over the wrist along the line of the third metacarpal, extending proximally from its midshaft. Subcutaneous tissue and skin are elevated sharply from the extensor tendons and retracted medially and laterally using three zero silk retraction 15 sutures, with care to protect the superficial radial nerve and the dorsal cutaneous branch of the ulnar nerve. The extensor retinaculum is opened over the fourth compartment and raised medially and laterally. A dorsal synovectomy is carried out and the wrist extensors are checked for structural integrity.

To perform the ulnar head resection, which may be necessary to create a 20 larger flap for closure over the prosthesis, the capsule over distal ulna **14** is opened longitudinally. As shown in Figure 13, the distal one centimeter of the ulna

14 can be osteotimized and removed. A synovectomy of the ulnar compartments is then performed.

Referring now to Figures 14A – 15B, preparation of radius bone **12** will now be described. Using a bone awl (not shown), a hole is made through the articular surface of radius **12** about 5mm below its dorsal rim and just radial to Lister's tubercle. Enlarge the hole with a curette. Radial alignment guide rod **108** is inserted in the hole and advanced far into the medullary canal (Figure 14A). Fluoroscopy may be used to confirm that guide rod **108** is centered within the canal. Radial guide bar **110** is slid over the rod until it abuts the radius. Radial cutting guide block **112** (left or right) is mounted onto guide bar **110** and slid into proper position. It is positioned to guide the saw cut just beneath the articular surface (Figure 14B). While the curved under-surface of cutting block **112** is held aligned with the dorsal surface of radius bone **12**, two or three 1.1 mm K-wires **114** are inserted through the holes in cutting block **112** and drilled into the distal end of radius bone **12**. Cutting block **112** preferably has four rows of three holes spaced about 2.5 mm apart. By using the middle holes in the rows, cutting block **112** can be adjusted proximally or distally if the initial position was incorrect (Figure 14C).

Alignment rod **108** and guide bar **110** are removed and cutting block **112** is slid down along K-wires **114** against radius **12**. Lister's tubercle may have to be removed to fully seat the cutting block. K-wires **114** are cut a few millimeters above cutting block **112**. The position of cutting block **112** is checked for proper

level of resection and adjusted if needed. A small oscillating saw (not shown) is used to make the radial osteotomy. To complete the cut through the volar cortex, cutting block 112 may have to be removed. Cutting block 112 and K-wires 114 are removed.

5 Referring now to Figures 15A and 15B, the broaching of radius bone 12 will now be described. Alignment rod 108 is reinserted into the hole in radius bone 12. The proper size broach head 116 is inserted into broach handle 118 to the position for either "standard" or "minimal" broaching. Broach head 116 is slid over alignment rod 108 and its ulnar face is aligned parallel to the sigmoid notch of
10 radius bone 12 (Figure 15A). Using a mallet, broach head 116 is driven into the distal radius 12 until its collar is flush with the cut surface of radius 12 (Figure 15B).
Broach head 116 and alignment rod 108 are removed.

In order to determine the proper final implant size, a trial radial component 40 is inserted into radius bone 12 using the radial impactor 120, with care to
15 maintain proper alignment within the prepared metaphysis. The radial T-handle extractor tool 122 is applied and trial radial component 40 is removed.

Referring now to Figures 16A – 18B, preparation of carpus bone complex 32 will now be described. If scaphoid 16 and triquetrum 20 are mobile, carpus preparation is facilitated by first temporarily pinning these bones to capitate 24 and
20 hamate 22 bones in their best-reduced positions. K-wires are inserted through their distal portions just beneath the dorsal cortices to avoid interfering with the

osteotomy and the insertion of the carpal component implantation. Lunate **18** is excised by sharp dissection or rongeur.

Referring now to Figures 16A and 16B, carpal modular drill guide plate **124** corresponding to the selected implant size is inserted into carpal modular drill guide **123**. In applying drill guide **123**, guide plate **124** is rested on the dorsum of capitate **24**, the barrel is pressed against the capitate head, and the saddle is placed onto the 3rd metacarpal shaft **35** over the skin. For a "minimal" hole diameter for carpal component post **50**, the 2.5 mm drill bit is preferably used. While firmly holding drill guide **123**, carpal drill bit **125** is inserted into the barrel and a hole is made in capitate **24** to the depth marked on the bit corresponding to the implant size (x-small-16 mm, small-18 mm, medium-20 mm, large-22 mm). The counter-sink is used to enlarge the opening of the hole to accommodate the "shoulder" of the implant stem. For a "standard" hole diameter for carpal component post **50**, the sleeve for the guide wire is inserted in the drill guide barrel. The 1.4 mm guide wire is drilled through capitate **24** and into the 3rd metacarpal. The sleeve and drill guide are removed sequentially. The 3.5 mm cannulated drill is placed over the guide wire and a hole is made in capitate **24** to the proper depth corresponding to the implant size. The counter-sink is used to enlarge the opening of the hole.

Referring now to Figures 17A and 17B, the appropriate carpal guide bar **127**, for either a standard or minimal hole diameter, is inserted into the capitate

hole, drilled as described above, to its full depth. Carpal cutting guide block **126** is mounted onto guide bar **127** and slid into proper position. It is positioned to guide the saw cut through the proximal 1mm of hamate **22**, which will pass through the capitate **24** head, scaphoid **16** waist, and mid-body triquetrum **20**. While the

5 curved under-surface of the cutting block is held aligned with the dorsal surface of the carpus **32**, two to four 1.1mm K-wires **114** are inserted through the holes in cutting block **126** and drilled into the carpus. Carpal cutting block **126** preferably has four rows of two holes spaced about 2.5 mm apart. By using the distal holes in the rows, cutting block **126** can be adjusted distally to resect more carpus if the

10 initial position is incorrect.

K-wires **114** are cut a few millimeters above cutting block **126**. The position of cutting block **126** is checked for proper level of resection and to confirm that the cut will be made nearly perpendicular to the 3rd metacarpal shaft. A small oscillating saw (not shown) is used to make the carpal osteotomy (Figure 17B). To

15 complete the cut through the volar cortices cutting block **126** may have to be removed, but K-wires **114** should be retained. Cutting block **126** can be reapplied to help stabilize the carpal bones during the remaining carpal preparation.

Referring now to Figures 18A and 18B, in order to determine the proper final implant size, a trial carpal implant component **44** is inserted into the capitate

20 hold and its dorsal edge is aligned with the dorsal surface of the carpus. Carpal modular drill guide **123** (without the drill guide plate) is applied with its barrel in the

radial hole of carpal component **44** and its saddle on the 2nd metacarpal shaft **33** over the skin. A 2.5 mm hole is drilled across the scaphoid, trapezoid, and 2nd CMC joint to a depth (marked on the drill bit) of 30 to 35 mm (Figure 18A). This hole is typically not perpendicular to the carpal component, however the 5 component and screws heads are designed to accommodate screw insertions at oblique angles (see Figures 4E and 4F above). A 4.0 mm self-tapping trial screw **132** is inserted but not firmly tightened (Figure 18B).

A similar technique is used for the ulnar trial screw insertion, with a few important differences. The saddle is placed on the 4th metacarpal shaft **37** over 10 the skin. The 4th metacarpal must be held elevated (4th CMC extended) while drilling to ensure the hole is not directed volarly. The hole is drilled across the triquetrum and into the hamate but does not cross the mobile 4th CMC joint. Its depth is typically 20 mm but a small wrist may accommodate only 15 mm. A 4.0 mm self-tapping trial screw is inserted but not firmly tightened.

15 A trial reduction is then performed to verify all proper sizing of components prior to final implantation. Radial trial implant component **40** is reinserted into the medullary canal of radius bone **12**. A trial carpal bearing component **42** is slid over the carpal plate, beginning with the standard thickness, and the joint is reduced as shown in Figure 19 so that the range of motion and stability can be checked. The 20 prosthesis is typically quite stable and should demonstrate approximately 35° of flexion and 35° of extension with modest tightness at full extension. If the volar capsule is tight and limiting extension, the radius may need to be shortened and

re-broached using the previously described technique. If a preoperative flexion contracture was present, a step-cut tendon lengthening of the flexor carpi ulnaris and occasionally the flexor carpi radialis may be required to achieve proper balance and motion. When volar instability is present, the volar capsule is

5 inspected and if detached it is repaired to the rim of the distal radius. If the volar capsule is intact, a thicker polyethylene component may be required to increase soft tissue tension. A mild dorsal instability should respond to capsule closure but a thicker polyethylene is considered for marked instability. The wrist should easily stay in neutral position or in the balance state.

10 When performing a trial reduction, an alternative to the procedure described immediately above is to use a trial set comprising a trial carpal implant component, a trial radial implant component, and a trial radial implant component that are identical to the implant components which will be permanently implanted during the implant procedure. However, the trial set has the advantage of sizing nine

15 different trial carpal bearings during the trial process. After trial carpal component **44** and trial radial component **40** have been positioned, a trial bearing component **42** is slid over the carpal plate and the joint is reduced as shown in Figure 19. If the joint is too tight, the first bearing component is removed and a second trial bearing component is inserted, the second bearing component being of either an

20 increased dimension or a decreased dimension depending upon the results of the trial reduction. The trial bearing component can be made of an acetyl copolymer, a composite material, or any material having similar characteristics. The trial

carpal implant component is preferably made of titanium and the radial implant component is preferably made of a cobalt-chrome material. However, the carpal implant component or the radial implant component may be made of any material having similar characteristics, such as a composite material.

- 5 An advantage to using the trial set during a trial reduction is that the size of the bearing component may be precisely selected for the particular implant being performed. This eliminates the necessity of having to remove additional bone from the radial bone in order to achieve a proper fit of the implant. Another advantage of using the trial set during the trial reduction is that the trial set may be reused
- 10 after proper sterilization has been performed. Sterilization may include autoclaving or any sterilization method that would not dimensionally or physically affect the trial set.

Once a trial reduction is completed and the proper size implant decided upon, implantation must be performed in order to fixate the various components.

- 15 Remove the trial components and irrigate the wound thoroughly. Three horizontal mattress sutures of 2-0 polyester are placed through small bone holes along the dorsal rim of the distal radius for later capsule closure. If the ulnar head was resected, sutures are placed through its dorsal neck.

Next, carpal implant component **44** fixation is performed. First the wound is irrigated with pulsed lavage. Bone cement is introduced into the central peg hole in the capitate metacarpal complex. For example, in accordance with one embodiment this bone cement comprises methylemethacrylate. Carpal implant

- 20

post **50** is introduced into this hole and tapped all of the way in as shown in Figure 20 utilizing carpal plate impactor **128**. It is important to keep the implant flush with the bone margins. Care must be taken to remove excess cement, especially from the intracarpal region. It is also understood that carpal component fixation may

5 also be performed without the use of bone cement wherein carpal implant post **50** is press-fit or interference fit into the central peg hole in the capitate metacarpal complex through the use of an application of a beaded porous coating as described hereinabove.

The ulnar side of the plate is then drilled with a 2.5 millimeter bit. Two 4.5-millimeter screws **132** are then inserted through the peripheral holes in carpal planar base member **49**. The radial screw is longer and could cross the carpal space mediocarpal joint. Since the carpal mediocarpal joint of the fourth and fifth metacarpals are mobile, care should be taken to avoid crossing these joints (unless it is necessary for better purchase). Screws **132** help hold the fragment of

10 the triquetrum and the scaphoid in place and add strength to the carpal fixation.

Bone screws **132** shown in Figure 23 secure the hamate **22** and trapezoid **26, 28** bones respectively. These bone screws may comprise, for example, conventional 4.5-millimeter diameter bone screws that are between 20 and 40 millimeters in

15 length depending on the size of the implant and patient. Remove any remaining K-wires from the carpus. Cancellous bone grafts obtained from the radius and

20 resected carpal bones are packed into the defects between the carpal bones to obtain a uniform bony fusion.

To perform radial implant component **40** fixation, a bone plug is inserted into the medullary canal of the radius to act as a cement restricter. The canal is cleaned with pulse lavage and dried. Bone cement is mixed and injected into the canal using a syringe as shown in Figure 21A. The true radial component **40** is

5 then introduced into the medullary canal as shown in Figure 21B and is driven into the metaphysis using radial impactor **120**. It is important to remove all excess cement from the immediate area. Care is taken to place the prosthesis in a valgus position. A varus angle of the component will result in a post-operative ulnar deviation deformity of the hand. It is also understood that radial component **40**

10 fixation may also be performed without the use of bone cement wherein radial component stem **48** is press-fit or interference fit into the medullary canal of the radius through the use of an application of a beaded porous coating as described hereinabove.

The articulating bearing component **42** trial is applied to confirm the proper size. Once the correct size is verified, the bearing impactor (not shown) is placed over bearing component **42** and a firm impact is applied from a mallet in a linear motion. Bearing component **42** will snap into place when external lip **80** of socket protrusions **72** on carpal implant component **44** matingly join internal groove **106** of socket recesses **104** on bearing component **42**. Then, bearing component **42**

15 should be confirmed as completely engaged onto the carpal planar base member.

A final assessment of wrist motion, balance and stability can then be made.

Wound closure is accomplished by first closing the ulnar joint capsule tightly, thereby stabilizing the distal ulnar. The ECU tendon is brought dorsally to obtain additional stability. The capsule of the radial carpal joint is reattached to the distal end of the radius. If the capsule is deficient, one-half of the extensor 5 retinaculum is used to cover the defects. Meticulous closure of the capsule is mandatory to ensure stability in the post-operative. The hand is then immobilized in bulky dressing with the wrist in a neutral position for about two to three days.

Post-operative management initially involves strict elevation and early passive and active digital motion to reduce swelling. At approximately 10 days, the 10 sutures are removed and an x-ray is obtained to confirm prosthetic reduction. A removable plastic wrist splint is fabricated and used when not performing exercises. A gentle wrist exercise program can begin within the first two weeks, including active flexion and extension, radial and ulnar deviation, and pronation and supination. A therapist may be engaged to ensure progress. The splint is 15 discontinued at the 4th postoperative week and hand use advanced. The exercise program is continued and strengthening is added. Power grip and lifting is discouraged for the first 8 weeks. A dynamic splint is occasionally used if recovery of motion is difficult or incomplete. The patient is advised against impact loading of the wrist and repetitive forceful use of the hand.

20 Referring now to Figure 22, a pre-operative x-ray of a patient suffering from radio-carpal arthritis is shown. Figure 23 shows the same patient 32 months post-operatively now asymptomatic and with good functional range of motion.

Referring now to Figures 24 – 30, there are shown various views of an alternative embodiment **136** of the prosthetic wrist implant disclosed herein. In particular, the implant includes a radial implant component **138**, a carpal component **140** and a bearing component **142**. As can be seen in Figures 24 – 5 30, radial component **138** and bearing component **142** are similar to radial component **40** and bearing component **42** and respectively shown in Figures 2A and 2B. However, in this embodiment carpal component **140** does not have a carpal post **50**. Similarly, in accordance with another alternative embodiment (not shown), radial implant **136** may be secured using at least one screw that is 10 inserted through the radial component into the radial bone **12**.

It will be understood that various details of the present subject matter may be changed without departing from the scope of the subject matter. Furthermore, the foregoing description is for the purpose of illustration only, and not for the purpose of limitation.